UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/085,040	03/01/2002	Joseph C. Cauthen	08442.0002-04	8078

22852 7590 07/06/2006

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP
901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER	
ISABELLA, DAVID J	

ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 07/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/085,040	CAUTHEN, JOSEPH C.	
	Examiner	Art Unit	
	DAVID J. ISABELLA	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 May 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *102-107, 109-112,114-133, 137-139, 141, 142, 145-149, 151-175 and 179-181* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *102-107, 109-112,114-133, 137-139, 141, 142, 145-149, 151-175 and 179-181* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Response to Amendment

This amendment filed 5/31/2006 has been entered. The changes to the claims have been approved. All pending claims 102-107, 109-112,114-133, 137-139, 141, 142, 145-149, 151-175 and 179-181 are being considered for further examination on the merits.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 102,103,105-107,112,114,118,120,127,130,133,137,138,139,141, 142,145,147, 148, 149, 154-156, 160, 162, 172,175 and 179-181 are rejected under 35 U.S.C. 102(e) as being anticipated by of Akerfeldt [6596012].Akerfeldt discloses an occluder device that is structurally capable of being used to treat an intervertebral disc wall with all the elements of the claims.

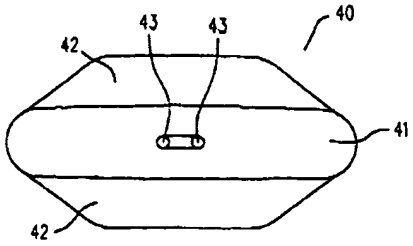

Fig 12

Fig 13

See figures 12 and 13 for the device (40) comprising a main body portion (41) and extension (42) having an axis projecting along a respective reference plane, which extends substantially laterally from the main body portion (41). See column 6, lines 22-35 for the extension (41) being constructed such that the axis can flexibly deflect from its respective reference plane.

The occluder **40** according to this embodiment comprises an elongated comparatively stiff central portion **41**. The shape of this portion **11** is such that it is slightly wider at the middle than at the ends, and also it is slightly thicker at the middle than at the ends, as can be clearly seen in FIGS. **11** and **12**. Furthermore, there are flexible side wings **42**, which are substantially thinner than the central portion **41**. This enables bending of the wings **42** towards each other to form an essentially cylindrical like structure, fitting into a cylindrical tool, like the one disclosed in FIG. **8**. However, the occluder illustrated in FIG. **8** is bent or folded in an opposite manner compered to the manner the occluder according to the third embodiment should preferably be folded.

A retaining structure, e.g. a suture, is secured to the occluder by passing it through holes **43** in the thickest part of the central portion **41**.

See Figure 12 for at least one receptacle (43) that is configured such that it is capable of receiving a fixation element.

Claims 103 and 105, see column 6, lines 35-37.

Claim 106, the body portion has a definitive shape that is capable of providing the function as claimed.

Claim 107, see Figure 13 for the extension (42) being of substantially uniform thickness.

Claim 112, see column 5, lines 19-20 the main body portion (41), the extension (42) and receptacle (43) being formed as a unitary device.

Claims 114 ,118,120 and 127, see column 5, lines 33-35 for the device (40) comprising a biocompatible polymeric material; and see column 5, lines 33-35 for the device (40) comprising a biodegradable substrate.

Claim 130, see Figure 14, column 6, lines 22 for the device (40) being flexibly resilient.

Claim 133, see Figure 12, columns 2-3, lines 67-2, and column 6, lines 22-35 for the main body portion (41) being shaped such that it is capable of forming a compatible fit with the edges of at least a portion of an aperture in an intervertebral disc wall.

Claims 137-139, see first and second extensions (42) in Figures 12 and 13.

Claim 142, see Figure 12 for the receptacle (11) comprising a slot.

Claims 145 and 147, see column 6, lines 35-37.

Claim 148, see Figure 12, columns 2-3, lines 67-2, and column 6, lines 22-35 for the main body portion (41) being shaped such that it is capable of forming a compatible fit with the edges of at least a portion of an aperture in an intervertebral disc wall.

Claim 149, see Figure 13 for the extension (42) being of substantially uniform thickness.

Claims 154 and 155, see column5, lines 19-20 the main body portion (41), the extension (42) and receptacle (43) being formed as a unitary device.

Claims 156 and 162, see column 5, lines 33-35 for the device (40) comprising a biocompatible polymeric material.

Claim 160, see column 5, lines 33-35 for the device (40) comprising a biodegradable substrate.

Claim 172, see Figure 14, column 6, lines 22 for the device (40) being flexibly resilient.

Claim 175, see column 5, lines 22+ for the extension being reversibly deformable to allow, in use, insertion into an aperture of an intervertebral disc and subsequent expansion from its compressed configuration, thereby conforming the device (40) to the shape of a portion of the inner wall of an annulus. Although Akerfeldt does not disclose using the device in this manner, the device is structurally capable of being used in this manner.

Claim 179, see Figure 13 for first and second extensions (42).

Claims 180 and 181, see Figure 13 for the respective axes of the first and second extensions (42) lying in the same reference plane when the extensions (42) are undeflected.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 104,108-111,113,115,116,117,119,121-126,128,129,131,132,146, 151-153, 157-159, 161 and 163-171 are rejected under 35 U.S.C. 103(a) as being unpatentable over Akerfeldt [6596012] in view of Gilson [5904703] and Bao et al. (USPN 6,224,630).

Akerfeldt discloses an occluder device that is structurally capable of being used to treat an intervertebral disc wall with all the elements of claims 102 and 141, but is silent to the device further comprising biodegradable surgical sutures, as required by claims 104 and 146, barbs, tension bands and staples, as required by claims 151-153, and a polymeric mesh, as required by claim 165. Bao et al. teaches an occluder device for biological apertures, wherein the device can be used for the treatment of an intervertebral disc wall (column 2, lines 58-61). Biodegradable sutures, staples, and

barbs (tines), as well as polymeric meshes, are disclosed as anchoring means in order to enhance short-term fixation of the device to the disc annulus, which will prevent migration of the device. See column 14, lines 15-30. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Bao et al. to modify the occluder device of Akerfeldt by including anchoring means in the form of biodegradable surgical sutures (claims 104,146), which also provide as tension bands (claim 152), barbs (claim 151), staples (claim 153), or polymeric meshes (claim 165) to the device (40) in order to enhance short-term fixation and prevent migration of the device (40). It is obvious that the sutures would comprise at least one knot because it is well known to knot sutures to prevent them from coming out or pulled apart (claims 105 and 147). When the device (40) of Gilson, as modified by Bao et al., is used to treat an intervertebral disc wall, short-term fixation will be to the disc annulus.

Gilson teaches that the occluder device (60) is made from a compressible, porous polymeric foam in column 4, lines 30-31 and 55-58. Bao et al. teaches the occluder device also being made from a compressible, porous polymeric foam in column 3, lines 15-19 and column 5, lines 36-42. The foam can be made from bioresorbable collagen fibers (claims 157 and 167; column 6, lines 40-43), interwoven biocompatible polymeric fibrils that by nature provide a membrane, fabric or sheet (claims 158, 159, 163, 164 and 166; column 7, lines 34-37), or ePTFE (claim 161; column 5, lines 56-57). These materials can be made sufficiently porous to permit tissue ingrowth into the material from surrounding tissue of the implant site. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention

to look to the teachings of Bao et al. to make the polymeric material of the device (40) of Akerfeldt from the materials required by claims 157-159, 161, 163, 164, 166 and 167 in order to make the foam with sufficient porosity to permit tissue ingrowth into the material from surrounding tissue of the implant site. When the device (40) of Akerfeldt, as modified by Gilson and/or Bao et al., is used to treat an intervertebral disc wall, the material of the device will facilitate regeneration of disc tissue (claim 169) by promoting tissue ingrowth from the surrounding annulus. Bao et al. also teaches making the foam from a hygroscopic material in order to initially secure the expanded device within the aperture (claim 168; column 3, lines 8-10), and including a bioactive silica-based material or a growth factor to the occluder device material in order to actively facilitate tissue ingrowth and/or improve the biocompatibility of the device (claims 170 and 171; column 9, lines 12-40).

Gilson discloses an occluder device that is structurally capable of being used to treat an intervertebral disc wall with all the elements of claim 102, but has extension at the proximal portion of the device. See Figure 14 for the device (60) comprising a main body portion (6) and an extension (5) having an axis projecting along a respective reference plane, which extends substantially laterally from the main body portion (6). See column 6, lines 20-23 for the extension (5) being constructed such that the axis can flexibly deflect from its respective reference plane. Bao et al. teaches an occluder device for biological apertures, wherein the device can be used for the treatment of an intervertebral disc wall (column 2, lines 58-61). Fixation elements in the form of biodegradable sutures, staples, and barbs (tines), as well as polymeric meshes, are

disclosed as extending at least partially into annular tissue in order to enhance short-term fixation of the device to the disc annulus, which will prevent migration of the device. See column 14, lines 15-30. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Bao et al. to modify the occluder device of Gilson by including fixation elements configured to extend at least partially into annular tissue and in the form of biodegradable surgical sutures (claims 103 and 104), which also provide as tension bands (claim 110), barbs (claim 109), staples (claim 111), or polymeric meshes (claim 123) to the device (60) in order to enhance short-term fixation and prevent migration of the device (60). It is obvious that the sutures would comprise at least one knot because it is well known to knot sutures to prevent them from coming out or pulled apart (claim 105). When the device (40) of Akerfeldt, as modified by Gilson and/or Bao et al., is used to treat an intervertebral disc wall, short-term fixation will be to the disc annulus.

With respect to claim 113, when the fixation element in the from of polymeric meshes of Bao et al. are applied to the exterior surface of the device (60) of Gilson, the main body portion (6), extension (5) and fixation element will be formed as a unitary device.

Claim 131, see column 4, lines 55-58 for at least a portion of the device (60) of Gilson being porous.

Claim 132, see column 4, lines 44-51 for the sleeve (11) portion of the device (60) of Gilson being non-porous.

With respect to claims 115-117, 119, 121-126,128,129,131,132, see rejection of claims 157-159, 161, 163, 164 and 166- 171, supra.

Claim 173, see column 4, lines 55-58 for at least a portion of the device (60) of Gilson being porous.

Claim 174, see column 4, lines 44-51 for the receptacle (11) portion of the device (60) of Gilson being non-porous.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID J. ISABELLA whose telephone number is 571-272-4749. The examiner can normally be reached on MONDAY-FRIDAY.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, CORRINE MCDERMOTT can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DAVID J ISABELLA
Primary Examiner
Art Unit 3738

DJI
6/27/2006